

# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,514	08/30/2005	Martin Eilers	930008-2195	2223
7590 08/21/2007 Ronald R Santucci			EXAMINER	
Frommer Lawrence & Haug 745 Fifth Avenue New York, NY 10151		PACKARD, BENJAMIN J		
			ART UNIT	PAPER NUMBER
			1609	
			MAIL DATE	DELIVERY MODE
			08/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)		
Office Action Comments	10/521,514	EILERS ET AL.		
Office Action Summary	Examiner	Art Unit		
	Benjamin J. Packard	1609		
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).		
Status				
Responsive to communication(s) filed on  2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This  3) ☐ Since this application is in condition for allowan closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro			
Disposition of Claims				
4)	vn from consideration. election requirement.  r. epted or b) □ objected to by the Edrawing(s) be held in abeyance. See	37 CFR 1.85(a).		
11) The oath or declaration is objected to by the Exa		• •		
Priority under 35 U.S.C. § 119				
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>				
Attachment(s)	_			
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary ( Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	te		

Art Unit: 1609

#### **DETAILED ACTION**

#### Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11,13, and 15-17, drawn to the use of modulators of the signal transduction pathway for the treatment of tumor diseases. Note: Species election required.

Group II, claim(s) 12 and 14, drawn to the use of modulators of the signal transduction pathway in the production of a medicant. Note: Species election required.

Note: While use claims are non-statutory under 35 USC 101, they are being treated as method claims for this restriction/species election.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The apparent special technical feature would appear to be the modulator of the signal transduction pathway. Claim 6 notes the modulator may be an inhibitor of Rhokinase. The specification on page 15 then states there are prior known Rho-inhibitors, which precludes the modulator as the special technical feature. Instead, it would appear the special technical feature is the <u>use</u> of the modulators for the treatment of trumor diseases and the <u>use</u> of the modulators <u>in the production</u> of a medicament.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For Group I: select a specific specie for each;

- A. the modulator of the signal transduction pathway of claim 1,
- B. whether there is a protecting group,
- C. if a protecting group is elected, the pharmacologically acceptable protecting group(s) of claim 16, and
- D. the method of administering of claim 17.

For Group II: select a specific specie for the modulator of the signal transduction pathway.

Applicant is required, in reply to this action, to elect a disclosed single species for each specie to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Art Unit: 1609

The claims are deemed to correspond to the species listed above in the following manner:

All claims refer to a modulator of the signal transduction pathway, claim 16 refers to pharmacologically acceptable protecting group(s), and claim 17 refers to various methods of administration.

The following claim(s) are generic: 1, 12, 16, and 17.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Species I is directed to activators and inhibitors of differing proteins. Species II is directed to protecting groups. Species III. is directed to methods of administration which vary in the biological reactivity.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

## Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin J. Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 9-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/521,514 Page 6

Art Unit: 1609

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

8 August 2007

ARDIN H. MARSCHEL SUPERVISORY PATENT EXAMINER